

REMARKS

Claims 1-18, 21, 24-34 and 36-38 are currently pending in the application, as amended. Claim 1 has been amended to more positively recite that “the instrument further includ[es] a unique identification code that provides positive unique identification of each test result provided by the instrument.” Support for the amendment to claim 1 can be found in, among other places, the original claims, such as claim original claims 1 and 35; the original Specification at paragraph [041]; and in Figs. 4A-4B. Accordingly, no new matter has been added.

Rejections Under 35 U.S.C. § 112

Claims 1-18, 21, 24-34 and 36-38 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because the Examiner alleges that the language added to claim 1 by amendment was not described in the Specification in a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-18, 21, 24-34 and 36-38 have also been rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, because the Examiner is unclear what “positive identification of all test results” was referring to.

Applicants respectfully traverse the Examiner’s characterization of the supporting description of the original disclosure.

In the last Amendment, filed October 14, 2004, the subject matter of original dependent claim 35 was added to independent claim 1, nearly verbatim. In particular, original claim 35 called for, “...the instrument includes a unique identification code to provide positive identification of all test results obtained using the instrument,” which is nearly the exact language that was added to the claim 1 except that “includes” was changed to “further including” to be grammatically correct.

The claims as filed in the original Specification are part of the disclosure, and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the

remainder of the specification, the applicant may amend the Specification to include the claimed subject matter. MPEP § 2163.06. Accordingly, paragraph [041] has been amended to include the language of original claim 35.

Paragraph [041] and Figs. 4A-4B, as originally submitted, provided sufficient support for the amendment to claim 1. In particular, paragraph [041] recites:

[041] Another general purpose input/output pin/port of the microprocessor 500 is connected to a unique identification tag circuit 522. The unique identification tag circuit 522, includes a Dallas Semiconductor integrated circuit #DS2401 or other component, which establishes a unique identification code, like a digital serial number for the particular instrument 10. *The unique identification code is used in connection with test results and other data to permit positive, unique identification of the particular instrument 10, which provided the test result.* Thus, each instrument 10 includes a unique identification code to provide positive identification of all test results obtained using the instrument 10.
[emphasis added]

The language of original claim 35 makes explicit that the written description fully supports claim 1.

The original Specification clearly sets forth that the unique identification code is used in connection with the test results and other data to permit positive, unique identification of the particular instrument which provided the test result.

“Positive” is defined as “characterized by or displaying certainty, acceptance, or affirmation.” (The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company). “Unique” is defined as “being the only one of its kind.” Id. “Identification” is defined as “(a) the act of identifying, (b) the state of being identified.” Id. A “positive, unique identification” is therefore an affirmation of the identity provided with the test result/data by the unique identification code in a particular instrument (i.e., evidence that a particular instrument provided a particular test result). One skilled in the art would recognize the merits of being able to identify which instrument provided a particular test result (e.g., traceability and the like).

Accordingly, Applicants respectfully submit that claims 1-18, 21, 24-34 and 36-38 are in full compliance with 35 U.S.C. § 112, and therefore, the rejections under 35 U.S.C. § 112, first paragraph and second paragraph should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Rejection of Claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38

Claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over U.S. Patent No. 5,096,669 ("Lauks *et al.*," hereinafter, "Lauks") in view of U.S. Patent No. 6,153,085 ("Patko *et al.*," hereinafter, "Patko") and U.S. Patent No. 5,108,889 ("Smith").

Withdrawal of the rejection of claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

Claim 1

Claim 1, as amended, recites, *inter alia*:

a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells, each test cell containing a fluid to be tested, the instrument for performing a diagnostic test selected from said plurality of tests upon the fluid within a selected test cell, the instrument including a reader which reads indicia on the selected test cell prior to engagement of the test cell, the diagnostic test to be performed being selected by the instrument based upon identification information obtained from the indicia on the selected test cell, the instrument further including a unique identification code that provides positive identification of each test result provided by the instrument....
[underline emphasis added]

Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result provided by the instrument.

The Examiner implicitly acknowledges that Lauks and Patko each fail to disclose a unique identification code for an electronic test instrument, in general, because the Examiner relies on Smith to attempt to provide such a unique identification code (actually a serial number in Smith). The Examiner points to column 52, line 66 through column 53, line 8 of Smith which recites:

A reset at 800 occurs when the system is first powered up and each time the lancet firing button 116 is pressed. If both F and S buttons, at 802, are pressed, the SET UP mode at 804 is entered. *The SET UP mode at 804 will be used at the factory or other locations to customize each instrument as to the specific characteristics. These characteristics may include, but are not limited to: serial number, date of manufacture, type of analyte, 12 or 24 hour clock, United States or International display format, units of concentration, look up tables, etc.* [emphasis added]

At best, this language cursorily suggests that the “assay instrument” of Smith *has* a serial number for identifying an assay instrument. However, Smith fails to disclose or suggest that such a serial number is used to identify which instrument provided a particular test result or provided other data.

The Examiner also points to column 56, lines 57-65 suggesting that the instrument has a serial number. In particular, the “SET UP” mode is described and merely suggests that in SET UP mode, the characteristics of the instrument may be customized (changed) including the serial number and date of manufacture. Column 56, lines 46-65 recite:

The user advances the packet 350 of sensors 352 and removes the insert tab 354 or the previously used sensor 352. See FIG. 5. When the user presses the lancet triggering button 116, the magnet 301 mounted on the side of button 116 moves with button 116 away from the proximity of normally-closed magnetic reed switch S3. The resulting closure of S3 drops the voltage on reset pin RT of microcontroller MC 750. As per the software flow chart of FIG. 30, the circuitry 336 enters either the SET UP mode 804, if both button switches S1 and S2 are pressed, or into the MEASUREMENT mode if not. *In the SET UP mode 804, digital information present at the sensor connector J1 (FIG. 28) will be downloaded into microcontroller memory. This mode is used at the factory or other locations to customize the characteristics of each instrument. These characteristics may include, but are not limited to, serial number, date of manufacture, type of analyte, 12 or 24 hour clock, United States or*

International display format, units of concentration, look-up tables, etc.
[emphasis added]

Here again, there is merely a cursory suggestion that the instrument *has* a serial number. But, there is no suggestion that the serial number is associated with the test data produced by a particular instrument. The two passages cited by the Examiner are the *only* two instances where the serial number is even mentioned in Smith.

To establish *prima facie* obviousness of a claimed invention, all the claim 's limitations must be taught or suggested by the prior art. M.P.E.P. § 2143.03. Lauks and Patko and modified by Smith fail to disclose or suggest all the claim limitations of claim 1. Modifying Lauks and Patko to include the serial number of Smith fails to disclose that the instrument has a unique identification code that provides positive identification of each test result provided by the instrument, as set forth in independent claim 1.

Moreover, as set forth in detail in the Amendment filed on October 14, 2004, the Applicants maintain that Lauks and Patko are not properly combinable. It is respectfully submitted that the Examiner has failed to identify *any objective teaching* in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead the individual to combine the relevant teachings of Lauks and Patko in the manner suggested by the Examiner. While the Applicants agree that it is the intention of Lauks to discard each sensor after it has been used once, it is respectfully submitted that there is no teaching or suggestion of any kind in the Lauks patent of any structure which would preclude or prevent a sensor from being used more than once. There is no unique serial number or other feature of the Lauks test cells which would permit a determination by the Lauks reader with respect to whether a test cell had been previously used. It is readily apparent from the Lauks patent that every test cell designed to perform a specific test will, by definition, have the *exact same* notch pattern. Thus, the Lauks reader has no basis of any kind to distinguish whether a test cell has been previously used. The Lauks patent is totally lacking in any suggestion or teaching regarding the desirability of precluding reuse of a test cell. It is respectfully submitted that such a linking teaching is just not present in the Lauks patent. Likewise, the Examiner has cited no linking teaching in the Patko patent which would in any way suggest that the storage of a unique serial number within a

barcode on the Patko test cell could or should in any way be adapted for use in a test cell of the type disclosed in the Lauks patent. Not only has the Examiner not pointed to any specific linking teaching in the Patko patent, it is respectfully submitted that no such linking teaching is present in the Patko patent.

The Examiner, in the alternative, suggests that if the new claim language is referring to storing the identification code with each data file, then it would have been obvious to store an instrument's identification code with each data file. The Examiner suggests that Lauks teaches that an instrument should have the capability of providing data and that Smith teaches that the instrument can have customized characteristics including units of operation and look-up tables. The Examiner asserts that it would have been obvious to have information about the instrument that prepared the data stored with the data files such that when the data is further processed, the operator analyzing the data would be able to determine both when and where the data was taken.

Applicants respectfully traverse the Examiner's assertion that the combination of Smith with Lauks provides the motivation to further modify the combined devices to uniquely identify test data produced by a particular instrument. Notably, Smith discloses that the instrument can transfer data using the audible generator output (see for example, column 55, lines 54-58: "[t]his mode TRANSMITS at 957 previously stored assay data via 300 baud Bell Telephone standard format."). Yet, there is no suggestion in Smith of using the serial number to be associated with particular test data sampled. Still the Examiner asserts that using the serial number from Smith and the customizable tables to modify Lauks, which did not include a serial number or other unique identifier for the instrument at all, would provide one with the motivation to modify the two references. Modifying Lauks to include the features of Smith results in a device that is already disclosed in Smith. The Examiner fails to point to any suggestion in either reference to further modify the combined device so that it associates a unique identification code with the test data to uniquely identify the particular instrument which produced particular test data.

Although a prior art device may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so. M.P.E.P. § 2143.01. Combing Smith and Lauks yields what is already disclosed in Smith sans any motivation to modify the combined device beyond what Smith discloses. As mentioned

above, Smith fails to recognize that the instrument has a unique identification code that provides positive identification of each test result provided by the instrument.

While any judgment of obviousness is based on hindsight reasoning, it is only permissible to take into account knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and without including knowledge gleaned *only* from the Applicants' disclosure. M.P.E.P. § 2145, X, A. It appears that the Examiner has impermissibly relied on the Applicants' disclosure in order to modify the Smith and Lauks device, and therefore, the further modification of the Smith and Lauks device and/or the combination of Lauks, Smith and Patko is not permissible as suggested by the Examiner.

Even modifying Lauks and Patko to include the serial number of Smith fails to disclose that the instrument has a unique identification code that provides positive unique identification of each test result provided by the instrument, as set forth in independent claim 1. Further, there is no suggestion in Lauks, Patko or Smith to further modify the instrument to provide positive unique identification of each test result provided by the instrument. Claims 2-12, 17-18, 21, 24, 26-28, 30 and 36-38 all depend from claim 1. Applicants respectfully submit that claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 are not *prima facie* obvious under 35 U.S.C. § 103(a) in view of Lauks and Patko and modified by Smith. Accordingly, Applicants respectfully request that the rejection of claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 13-16

Claims 13-16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Lauks, Patko and Smith and further in view of U.S. Patent No. 4,797,188 ("Tomita").

Withdrawal of the rejection of claims 13-16 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

Claims 13-16

Claims 13-16 are dependent upon independent claim 1.

As mentioned above with respect to claim 1 and as set forth in detail in the Amendment filed on October 14, 2004, the Applicants maintain that Lauks and Patko are not properly combinable. It is respectfully submitted that the Examiner has failed to identify any objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead the individual to combine the relevant teachings of Lauks and Patko in the manner suggested by the Examiner. The Lauks patent is totally lacking in any suggestion or teaching regarding the desirability of precluding reuse of a test cell. Likewise, the Examiner has cited no linking teaching in the Patko patent which would in any way suggest that the storage of a unique serial number within a barcode on the Patko test cell could or should in any way be adapted for use in a test cell of the type disclosed in the Lauks patent. Thus, the references lack any objective teaching which would lead to the combination suggested by the Examiner.

Further, for all of the reasons cited above with respect to claim 1, Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result provided by the instrument.

Tomita fails to compensate for the deficiencies of Lauks, Patko and Smith. Tomita merely discloses a sheet type electrode for use in measurement of ions and fails to disclose or suggest an electronic instrument having a unique positive identification code to associate with data acquired from such an electrode.

Applicants respectfully submit that claims 13-16 are not *prima facie* obvious under 35 U.S.C. § 103(a) in view of Lauks, Patko, Smith and Tomita. Accordingly, Applicants respectfully request that the rejection of 13-16 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 25 and 27-29

Claims 25 and 27-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Lauks, Patko and Smith and further in view of U.S. Patent No. 4,798,705 ("Jakubowicz *et al.*," hereinafter, "Jakubowicz").

Withdrawal of the rejection of claims 25 and 27-29 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

Claims 25 and 27-29

Claims 25 and 27-29 are dependent upon independent claim 1.

As mentioned above with respect to claim 1 and as set forth in detail in the Amendment filed on October 14, 2004, the Applicants maintain that Lauks and Patko are not properly combinable. It is respectfully submitted that the Examiner has failed to identify any objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead the individual to combine the relevant teachings of Lauks and Patko in the manner suggested by the Examiner. The Lauks patent is totally lacking in any suggestion or teaching regarding the desirability of precluding reuse of a test cell. Likewise, the Examiner has cited no linking teaching in the Patko patent which would in any way suggest that the storage of a unique serial number within a barcode on the Patko test cell could or should in any way be adapted for use in a test cell of the type disclosed in the Lauks patent. Thus, the references lack any objective teaching which would lead to the combination suggested by the Examiner.

Further, for all of the reasons cited above with respect to claim 1, Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result provided by the instrument.

Jakubowicz fails to compensate for the deficiencies of Lauks, Patko and Smith. Jakubowicz discloses a "compact analyzer" with a keyboard, a 4-line liquid crystal display and a thermal dot matrix printer. But, there is no suggestion in Jakubowicz that the compact analyzer has a unique identification code or that such a unique identification code be utilized with acquired/produced test data.

Furthermore, the proposed modification cannot render the prior art unsatisfactory for its intended purpose. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. M.P.E.P. § 2143.01.

Here, both Lauks and Smith are intended to be portable, hand held devices. For example, Lauks at column 10, lines 30-44 indicate that the reader is a hand held device and that the input/output port makes connection to external devices such as printers and computers. Likewise, Smith at column 18, lines 44-48, notes that the disposable sensor instrument is preferably similar in size and shape to a vest pocket flashlight to be stored in a pocket of the user. Accordingly, modifying either of these devices to include the keyboard, 4-line liquid crystal display and/or thermal dot matrix printer of the bench-top device of Jakubowicz would change the intended use of the devices as well, and therefore, the combination is not permissible either.

Applicants respectfully submit that claims 25 and 27-29 are not *prima facie* obvious under 35 U.S.C. § 103(a) in view of Lauks, Patko, Smith and Jakubowicz. Accordingly, Applicants respectfully request that the rejection of 25 and 27-29 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 31-34

Claims 31-34 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Lauks, Patko and Smith and further in view of U.S. Patent No. 5,405,510 ("Betts *et al.*," hereinafter, "Betts").

Withdrawal of the rejection of claims 31-34 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

Claims 31-34

Claims 31-34 are dependent upon independent claim 1.

As mentioned above with respect to claim 1 and as set forth in detail in the Amendment filed on October 14, 2004, the Applicants maintain that Lauks and Patko are not properly combinable. It is respectfully submitted that the Examiner has failed to identify any objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead the individual to combine the relevant teachings of Lauks and Patko in the manner suggested by the Examiner. The Lauks patent is totally lacking in any suggestion or teaching regarding the desirability of precluding reuse of a test cell. Likewise, the Examiner has cited no linking teaching in the Patko patent which would in any way suggest that the storage of a unique

serial number within a barcode on the Patko test cell could or should in any way be adapted for use in a test cell of the type disclosed in the Lauks patent. Thus, the references lack any objective teaching which would lead to the combination suggested by the Examiner.

Further, for all of the reasons cited above with respect to claim 1, Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result provided by the instrument.

Betts fails to compensate for the deficiencies of Lauks, Patko and Smith. Betts discloses a portable analyte measuring systems that can be AC or DC powered, that have batteries and that each have a central processing unit that communicates external via RS232. However, there is no suggestion in Betts that the portable analyte measuring systems have a unique identification code or that such a unique identification code be utilized with acquired/produced test data.

Applicants respectfully submit that claims 31-34 are not prima facie obvious under 35 U.S.C. § 103(a) in view of Lauks, Patko, Smith and Betts. Accordingly, Applicants respectfully request that the rejection of 31-34 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the foregoing Amendment and Remarks, it is respectfully submitted that claims 1-18, 21, 24-34 and 36-38, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

CHAD S. GEPHART et al.

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(Date)

By: John D. Simon, Reg. No. 52,225, for
LESLIE L. KASTEN, JR.
Registration No. 28,959
AKIN GUMP STRAUSS HAUER & FELD LLP
One Commerce Square
2005 Market Street, Suite 2200
Philadelphia, PA 19103-7013
Telephone: 215-965-1200, **Direct Dial: 215-965-1290**
Facsimile: 215-965-1210
E-Mail: lkasten@akingump.com

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